Emergency Manager's Frequently Asked Questions (FAQ) for COVID-19 Vaccine Distribution

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COVID-19 Vaccine Overview

How many different vaccines are there?

In the United States, the federal government's <u>Operation Warp Speed</u> has contracted with six different vaccine manufacturers to begin manufacturing their vaccine prior to receiving FDA approval or Emergency Use Authorization (EUA). The table below provides an overview of the vaccines.

Manufacturer	Doses needed	Timing	Storage/Handling
Moderna	2	0, 28 days	Frozen 30 days refrigerated
Pfizer/BioNTech	2	0, 21 days	Ultra-Cold Frozen 5 days refrigerated
AstraZeneca/Oxford	2	0, 28 days	Refrigerated
Novavax	2	0, 21 days	Refrigerated
Sanofi/GSK	2	TBD	Refrigerated
Johnson/Johnson & Johnson	1	N/A	Frozen 3 months refrigerated

Can a different vaccine for the second dose be used?

No, the vaccines are not interchangeable. Patients must receive the same manufacturer's vaccine for both doses.

How will people know to get a second dose of the vaccine?

Vaccine ancillary supply shipments include a COVID-19 vaccination card that should be given to every patient as a reminder from the provider. These cards will serve as a record of which vaccine was given and a reminder notice that a second dose will be needed. Additionally, public information and education materials will be disseminated regarding the importance of a second dose.

How long does immunity last? Will this vaccine be needed every year, like a flu shot?

At this time, it is unknown how long immunity will last after vaccination or if annual boosters will be needed. The CDC's Advisory Commission on Immunization Practices will issue guidance on any follow-up vaccinations as this data becomes available.

Is this vaccine for children?

Initially, the vaccine will only be approved for adult populations and not targeted to minors. In October 2020, Pfizer expanded their clinical trial to children 12 and older, however, their initial submission for an Emergency Use Authorization (EUA) is

for use only in adults. Additional manufacturers may also expand their clinical trials to minors.

How do we know the vaccine is safe?

Vaccines undergo extensive trials to test both safety and efficacy before being released to the public. Additionally, the federal government has multiple safety programs that help monitor COVID-19 vaccine safety after authorization. For more information, see the CDC's <u>website</u>.

Should people who tested positive for COVID-19 be vaccinated?

The state is waiting on guidance from the vaccine manufactures and the CDC.

Vaccine Distribution and Allocation

How many doses of the vaccine will Texas get?

CDC has stated that Texas will receive a pro rata share based on vaccines available in the US at the time of FDA approval or EUA. Other drug makers in Phase 3 trials are expected to have vaccines available early in the new year.

How will COVID-19 vaccine shipments be transported?

Most vaccines will be shipped from McKesson directly to the provider using commercial shipping companies. In the case of the ultra-cold vaccine, it will be shipped straight from the manufacturer, Pfizer. All ancillary supply kits will be shipped from McKesson. Vaccine and ancillary supplies are shipped separately.

Do shipments of vaccine need security or law enforcement escorts?

Local jurisdictions may work with their local law enforcement to provide security as appropriate.

What is the minimum number of doses a provider can order?

The table below shows minimum order quantities for each manufacturer's vaccine.

Manufacturer	Number of Doses in Minimum Order
Moderna	100
Pfizer/BioNTech	975
AstraZeneca/Oxford	100
Johnson/Johnson & Johnson	100
Novavax	100
Sanofi/GSK	100

What ancillary supplies will be provided with vaccine orders?

The Operation Warp Speed will separately ship the following ancillary supplies to the provider per 100 doses in the order:

- 105 needles for vaccine administration
- 105 syringes
- 210 alcohol prep pads
- 4 surgical masks and 2 face shields
- 100 COVID-19 vaccination record cards
- Vaccine needle guide
- Reconstitution Kit with necessary supplies for vaccines requiring dilution

How can I order the COVID-19 vaccine?

Providers must be properly registered to receive vaccine. For more information, see DSHS's website.

How much will it cost to receive COVID-19 vaccine?

COVID-19 vaccines and ancillary supplies will be distributed by the federal government at no cost to enrolled COVID-19 vaccination providers.

What criteria is being used to determine the order of vaccination for the public? Who can get vaccinated?

Based on recommendations from the CDC Advisory Committee on Immunization Practices (ACIP) and the Expert Vaccine Allocation Panel (EVAP), Texas will initially allocate COVID-19 vaccines based on the following criteria:

- Protecting health care workers who fill a critical role in caring for and preserving the lives of COVID-19 patients and maintaining the health care infrastructure for all who need the vaccine.
- Protecting frontline workers who are at greater risk of contracting COVID-19 due to the nature of their work providing critical services and preserving the economy.
- Protecting vulnerable populations who are at greater risk of severe disease and death if they contract COVID-19.
- Mitigating health inequities due to factors such as demographics, poverty, insurance status and geography.
- Data-driven allocations using the best available scientific evidence and epidemiology at the time, allowing for flexibility for local conditions.
- Geographic diversity through a balanced approach that considers access in urban and rural communities and in affected zip codes.
- Transparency through sharing allocations with the public and seeking public feedback.

Eventually, anyone who chooses to be vaccinated will have access to the vaccine.

Who is getting vaccinated first?

Protecting health care workers is essential to keeping the health care system intact and able to care for COVID-19 and other patients, so phase 1A of vaccine distribution, when the vaccine supply is most limited, will focus on making vaccine available to health care workers. Texas' Expert Vaccine Advisory Panel has recommended, and the Commissioner of Department of State Health Services, John Hellerstedt has approved, health care workers likely to provide direct care for COVID-19 patients and other vulnerable residents to be the first group to receive the vaccine. This includes:

Staff at hospitals and long-term care facilities

- Emergency Medical Services
- Home health care workers

EVAP has produced detailed $\underline{\text{definitions}}$ of health care workers for the purposes of vaccination.

What health care workers are eligible to get vaccinated?

Due to anticipated supply limitations, Phase 1A, where health care workers will be vaccinated, is divided in to two <u>tiers</u>.

First Tier	Second Tier
Hospital staff working directly with patients who are positive or at high risk for COVID-19. Includes: a. Physicians, nurses, respiratory therapists and other support staff (custodial staff, etc.) b. Additional clinical staff providing supporting laboratory, pharmacy, diagnostic and/or rehabilitation services	Staff in outpatient care offices who interact with symptomatic patients. Includes: a. Physicians, nurses, and other support staff (custodial staff, etc.) b. Clinical staff providing diagnostic, laboratory, and/or rehabilitation services c. Non 9-1-1 transport for routine care
Long-term care staff working directly with vulnerable residents. Includes: a. Direct care providers at nursing homes, assisted living facilities, and state supported living centers b. Physicians, nurses, personal care assistants, custodial, food service staff	Direct care staff in freestanding emergency medical care facilities and urgent care clinics
EMS providers who engage in 9-1-1 emergency services like pre-hospital care and transport	Community pharmacy staff who may provide direct services to clients, including vaccination or testing for individuals who may have COVID
Home health care workers, including hospice care, who directly interface with vulnerable and high-risk patients	Public health and emergency response staff directly involved in administration of COVID testing and vaccinations
	Last responders who provide mortuary or death services to decedents with COVID-19. Includes: a. Embalmers and funeral home workers who have direct contact

First Tier	Second Tier
	with decedents b. Medical examiners and other medical certifiers who have direct contact with decedents
	School nurses who provide health care to students and teachers

What other populations will have priority access to the vaccine?

The CDC's <u>Advisory Committee on Immunization Practices</u> (ACIP) has identified vulnerable and frontline populations that will have priority access to the vaccine. The <u>Expert Vaccine Advisory Panel</u> (EVAP) will make decisions regarding when each of these population swill receive the vaccine. The identified populations are:

- Health care personnel
- Other frontline workers (may include public safety, firefighting, education, food and agriculture, and other sectors as defined by the EVAP)
- Long-term care facility residents
- People with underlying medical conditions
- People 65 years of age and older
- People from racial and ethnic minority populations
- People from tribal communities
- People who are incarcerated/detained
- People experiencing homelessness/living in shelters
- People living and working in other congregate settings
- People living in rural communities
- People with disabilities
- People who are uninsured or underinsured

When will a specific population [first responders, educators, seniors, utilities workers, etc.] be able to get vaccinated?

Texas' Expert Vaccine Advisory Panel (EVAP) will continue to meet throughout the distribution process and will make recommendations on how and when to roll out vaccines to other critical groups.

Are there any special considerations for long term care facilities?

Operation Warp Speed (OWS) has partnered with CVS and Walgreens to provide vaccination services for the residents of long-term care facilities. Most facilities in Texas have registered for this service.

- Local health departments can contact DSHS for information on which facilities are registered. Emergency managers are encouraged to work with their local health department to determine if any facilities in their jurisdiction have not registered.
- OWS has matched facilities with partner pharmacies. Pharmacies will work directly with their facilities to schedule vaccination.
- Facility staff who have not already been vaccinated as part of healthcare worker vaccination will be eligible for vaccination as part of this program.

Local EM Role

What is the role of local emergency management?

Local emergency managers are a critical partner in supporting the vaccination distribution program. Local emergency managers may support vaccination in their communities by partnering with local health departments. For more information, see TDEM's Local Emergency Manager's Guide to COVID-19 Vaccine Distribution.

How can I find out what providers are registered to administer the vaccine?

Contact your <u>local or regional public health department</u>. They have access to the list of registered providers in your area.

Should we plan to organize Points of Dispensing (PODs) like in a Strategic National Stockpile (SNS) distribution?

There are key differences between SNS PODs and COVID-19 vaccination PODs. COVID-19 vaccination PODs must follow all CDC and DSHS requirements for vaccination storage, handling, administration, and reporting. Existing POD plans can, however, be adapted to suit COVID-19 vaccination needs. For more information, see TDEM's Local Emergency Manager's Guide to COVID-19 Vaccine Distribution.

Can we use STAR requests to order vaccine?

No. Vaccine will only be distributed via the CDC/DSHS distribution process to properly enrolled providers.

What state assistance can we request?

STAR requests may be submitted for any other kind of vaccination support. Examples of requested supplies may include:

- Data logger for temperature monitoring
 - For the ultra-cold vaccine only, providers will be able to use the data logger that comes with the thermal shipper. This will only work for storing the vaccine in the shipper. For more details on the ultra-cold vaccine storage and handling, see below.
- Nitrile/latex gloves
- Additional dry ice beyond the first shipment
 - The first shipment of dry ice to replenish ultra-cold shipping containers once upon arrival will be provided
- Sharps containers
- Bandages/gauze/tape

Provider Enrollment/Vaccine Administration

Can I register to become a COVID-19 vaccine provider?

A licensed signing clinician will be required to enroll in the COVID-19 Vaccine Program. Licensed signing clinicians include medical doctors (MD), Doctors of Osteopathic Medicine (DO), nurse practitioners (NP), advanced practice nurses (APN), physician assistants (PA), Certified Nurse Midwives (CNM), dentists (DDS), and registered pharmacists (RPh). They must have an Individual National Provider Identification Number (NPI), and they must register though the EnrollTexasIZ.dshs.texas.gov web site. The EnrollTexasIZ site has detailed information on the registration process and requirements. For questions about registration, please call the DSHS COVID-19 Vaccine Provider hotline at (877) 835-7750, 8 a.m. to 5 p.m., Monday through Friday or email COVID19VacEnroll@dshs.texas.gov.

What are the requirements for COVID-19 vaccine providers?

COVID-19 vaccine providers must follow all requirements established by CDC and DSHS. For more information, see DSHS' provider website.

What are the reporting requirements?

Vaccine providers are required to report COVID-19 vaccine administration data to the Texas Immunization Registry (ImmTrac2). Vaccine providers need to be registered to use that system. For more information, see DSHS's <u>website</u>.

How can I get training in ImmTrac2?

DSHS manages all aspects of ImmTrac2. DSHS has a variety of training videos related to ImmTrac2 on their website. For additional questions related to ImmTrac2 contact DSHS at ImmTrac2 @dshs.texas.gov or 800-252-9152.

Where can I get more information about becoming a vaccine provider?

DSHS is overseeing the provider enrollment process. Please visit their <u>website</u>, <u>Frequently Asked Questions</u>. You can also contact the DSHS COVID-19 Vaccine Provider hotline at (877) 835-7750, 8 a.m. to 5 p.m., Monday through Friday or email <u>COVID19VacEnroll@dshs.texas.gov</u>.

Is there a deadline for providers to enroll in the COVID-19 vaccination program?

Enrollment for the COVID-19 Vaccine Program is now open for providers and can be accessed through EnrollTexasIZ.dshs.texas.gov. There is no close date at this time for providers to enroll in the COVID-19 Vaccine Program.

Who can and who cannot administer the COVID-19 vaccine?

Any medical professional is eligible to administer the COVID-19 vaccine, including but not limited to licensed nurses, medical assistants, emergency medical services (including paramedic or EMT), or staff members granted authority to vaccinate by assigning clinician. Additional medical professionals (e.g. RNs, LVNs, EMTs, Certified Medical Assistant) can administer the COVID-19 vaccine as authorized by the signing clinician for the vaccine provider.

Will emergency medical service (EMS) personnel be allowed to administer the vaccine?

Any medical professional is eligible to administer the COVID-19 vaccine, including but not limited to licensed nurses, medical assistants, emergency medical services (including paramedic or EMT), or staff members granted authority to vaccinate by assigning clinician. Additional medical professionals (e.g. RNs, LVNs, EMTs, Certified Medical Assistant) can administer the COVID-19 vaccine as authorized by the signing clinician for the vaccine provider.

Are providers responsible for monitoring who qualifies for vaccination within an individual level?

Providers are required to administer COVID-19 vaccine in accordance with all requirements and standards of CDC and CDC's Advisory Committee on Immunization Practices (ACIP), including recommendations on population prioritization. For more information, contact DSHS' COVID-19 Vaccine Provider hotline at (877) 835-7750, 8 a.m. to 5 p.m., Monday through Friday or email COVID19VacEnroll@dshs.texas.gov.

How are we tracking who received which type of vaccine so as not to mix types of vaccine administered to an individual?

Individuals will receive an COVID-19 immunization record card during their first vaccine dose visit which will list the vaccine type and date administered. If the person does not have the card, the provider can check ImmTrac2 for the previous vaccine administration to validate vaccine type and date.

Can patients get a flu shot and a COVID-19 shot at the same time? If not, how long do they have to wait between each vaccine?

Patients should not get both vaccines simultaneously. Guidance on how long to wait between influenza (flu shot) and COVID-19 vaccines will be provided by the CDC.

Vaccine Storage and Handling

How does the vaccine need to be stored?

Each vaccine has unique storage requirements ranging from ultra-cold (-70°C/-90°F) to refrigerated (2-8°C/35-40°F).

Manufacturer	Storage/Handling
Moderna	Frozen (-20°C/-4°F) 30 days refrigerated (2-8°C/35-40°F)
Pfizer/BioNTech	Ultra-Cold Frozen (-70°C/-90°F) 5 days refrigerated (2-8°C/35-40°F)
AstraZeneca/Oxford	Refrigerated (2-8°C/35-40°F)
Johnson/Johnson & Johnson	Frozen(-20°C/-4°F) 3 months refrigerated (2-8°C/35-40°F)
Novavax	Refrigerated (2-8°C/35-40°F)
Sanofi/GSK	Refrigerated (2-8°C/35-40°F)

It is critical providers review and understand the manufacturers requirements for each individual vaccine. Improper storage temperatures will result in a non-viable vaccine supply. All COVID-19 vaccine supply is temperature-sensitive and need to meet proper cold chain requirements to maintain and ensure efficacy and maximize shelf life. For more information on proper vaccine storage and handling, visit the CDC Vaccine Storage and Handling Toolkit.

Will the manufacturer provide saline for reconstitution or is that part of the PPE/supply piece?

Yes, the saline solution, as well as appropriately sized needles, syringes, and alcohol prep pads for mixing will be sent with the ancillary supplies for the vaccines that require reconstitution.

Will vaccine and supplies come together or separate from the government/distributor?

Except for the Pfizer ultra-cold vaccine, the vaccines and supplies will be shipped directly to the vaccine provider by CDC's centralized distributor, McKesson. The ultra-cold vaccine will be shipped directly from the manufacturer, Pfizer, and the supplies will be shipped separately from McKesson.

What happens if the diluent or the cold chain is not maintained?

Providers should call the manufacturer listed on the box for viability determination. If the dose is deemed non-viable, then the doses should be reported as wasted. Instructions for returned wasted doses will be promulgated at a later time.

What training is available on how to handle the ultra-cold vaccine?

Training materials on handling the ultra-cold vaccine will be provided by the manufacturer and DSHS. Additional information will be provided as it becomes available.

Do we need to source dry ice?

For the Pfizer ultra-cold vaccine only, **one** shipment of dry ice and handling equipment will be automatically shipped to the provider to refresh the shipper upon arrival. If providers are planning to store the vaccine in the shipper for more than five days, additional dry ice must be supplied. Local jurisdictions are encouraged to locate their own sources of dry ice first but can request state assistance if no dry ice is available locally.

Should we purchase an ultra-cold storage unit?

The CDC does not recommend purchasing an ultra-cold freezer to receive the COVID vaccine. The vaccine can be stored in the shipper it comes in for up to 15 days and for an additional 5 days in the freezer. For more information on storage and handling of the ultra-cold vaccines, please review manufacturer guidance.

How can we store the vaccine in the thermal shipper?

The shipper will be shipped with 22kg of dry ice. The shipper must be opened upon receipt and the ice must be replenished within 24 hours. The shipper can only be opened for no more than twice (2 times) per day for up to three (3) minutes at a time. The shipper must be "re-iced" every five (5) days a maximum of three (3) times for a total of **15 days** of storage in the thermal shipper.

Are there any special materials being provided to handle or store the ultra-cold vaccine?

For the Pfizer ultra-cold vaccine only, one shipment of dry ice and handling equipment will be automatically shipped to the provider to refresh the shipper upon arrival. The shipment will include:

- Drv ice
- Tongs
- Thermal gloves
- Eye protection
- Instructions

Note, only enough dry ice for **one** "re-ice" will be provided. If providers are planning to store the vaccine in the shipper for more than five days, additional dry ice must be supplied.

Do I need a data logger for the ultra-cold vaccine?

If you are planning to store the vaccine in the thermal shipper, providers may need to use the data logger that is shipped from the vaccine manufacturer. Details and procedures for accessing this monitoring data are under development by the CDC.

If the provider is storing the vaccine in an ultra-cold freezer or refrigerator, you will need a data logger appropriate for those temperatures.